FDA Drug Approval Pathways 101

JUNE 29, 2022

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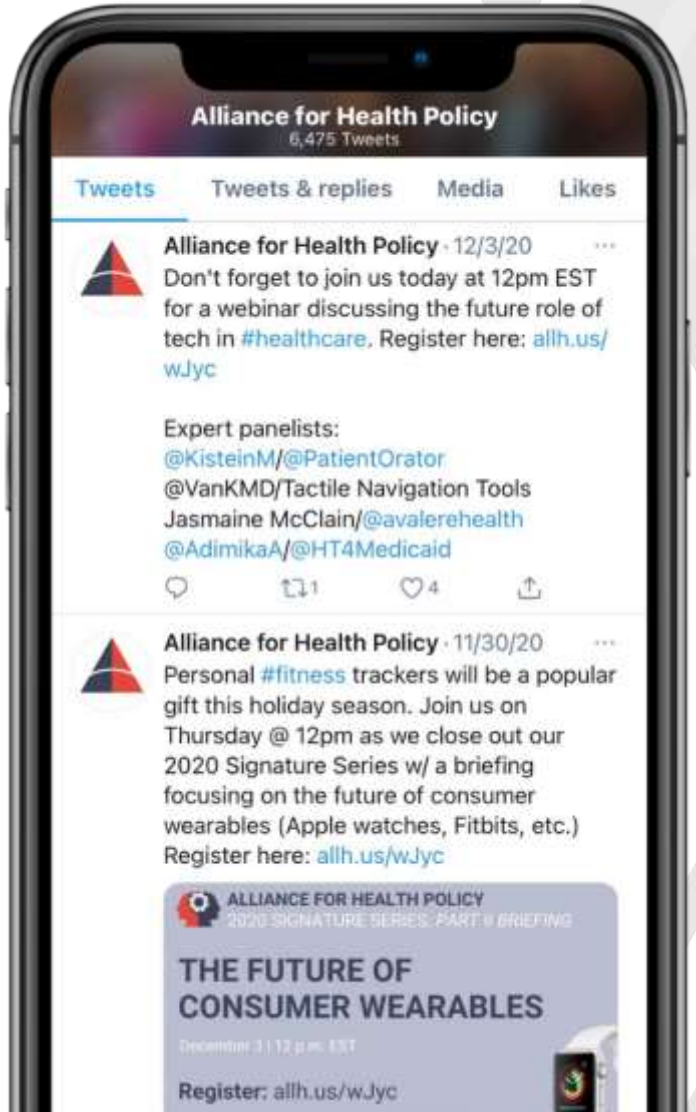

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FDA'S ROLE IN PROTECTING PATIENTS, PROVIDERS, & THE PUBLIC

Reshma Ramachandran, MD, MPP, MHS

Yale Collaboration for Research Integrity and Transparency (CRIT)

DISCLOSURES

- I have no relevant financial relationships with commercial entities that produce health-care related products or services relevant to the content of this presentation.
- My views are my own and not that of my employers (U.S. Government, U.S. Department of Veterans Affairs, Yale School of Medicine) nor the organizations I work with.
- I serve as a co-Director of the Yale Collaboration for Research Integrity and Transparency (CRIT), which is supported by Arnold Ventures
- I chair the Doctors for America FDA Task Force whose work is funded by the Laura and John Arnold Foundation. I also sit on the boards of the AMSA Foundation and Universities Allied for Essential Medicines North America.

FDA'S MISSION STATEMENT

- The Food and Drug Administration is responsible for protecting the public health by **ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices**; and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation.
- FDA also has responsibility for regulating the manufacturing, marketing, and distribution of tobacco products to protect the public health and to reduce tobacco use by minors.
- FDA is responsible for advancing the public health by **helping to speed innovations that make medical products more effective, safer, and more affordable** and by helping the public get the accurate, science-based information they need to use medical products and foods to maintain and improve their health.
- FDA also plays a significant role in the Nation's counterterrorism capability. FDA fulfills this responsibility by ensuring the security of the food supply and by fostering development of medical products to respond to deliberate and naturally emerging public health threats.

FDA'S FOOTPRINT

Regulates $0.25 of every $1 spent

Nearly 70% of every outpatient visit involves medication therapy

Nearly 80% of every hospital ER visit involves medication therapy

Percent of persons using at least 1 prescription drug in the last 30 days: 48.6% (CDC, 2015-2018)

Percent of persons using at least 3 or more prescription drugs in the past 30 days: 24% (CDC, 2015-2018)

Percent of persons using 5 or more prescription drugs in the past 30 days: 12.8% (2015-2018)

CHANGING FOCUS

Safety	• 1938 – Food, Drug, and Cosmetic Act
Safety & Efficacy	• 1962 – Kefauver-Harris Amendment
Safety, Efficacy, and Speed	• 1983 – Orphan Drug Act • 1984 – Hatch-Waxman Act • 1992 – Accelerated Approval • User Fee Reauthorizations • 21st Century Cures

WHAT DOES THE FDA DO?

- Approves drugs, devices, and other medical products as safe and effective for "conditions of use prescribed or suggested within the drug label"★
  - Specified indication
  - Specified population
  - Dose and duration of drug studies
- Burden on sponsors to demonstrate that the drug is safe and effective for proposed use within application
- FDA issues guidance for sponsors regarding standards for regulatory review, which sets parameters for safety and efficacy

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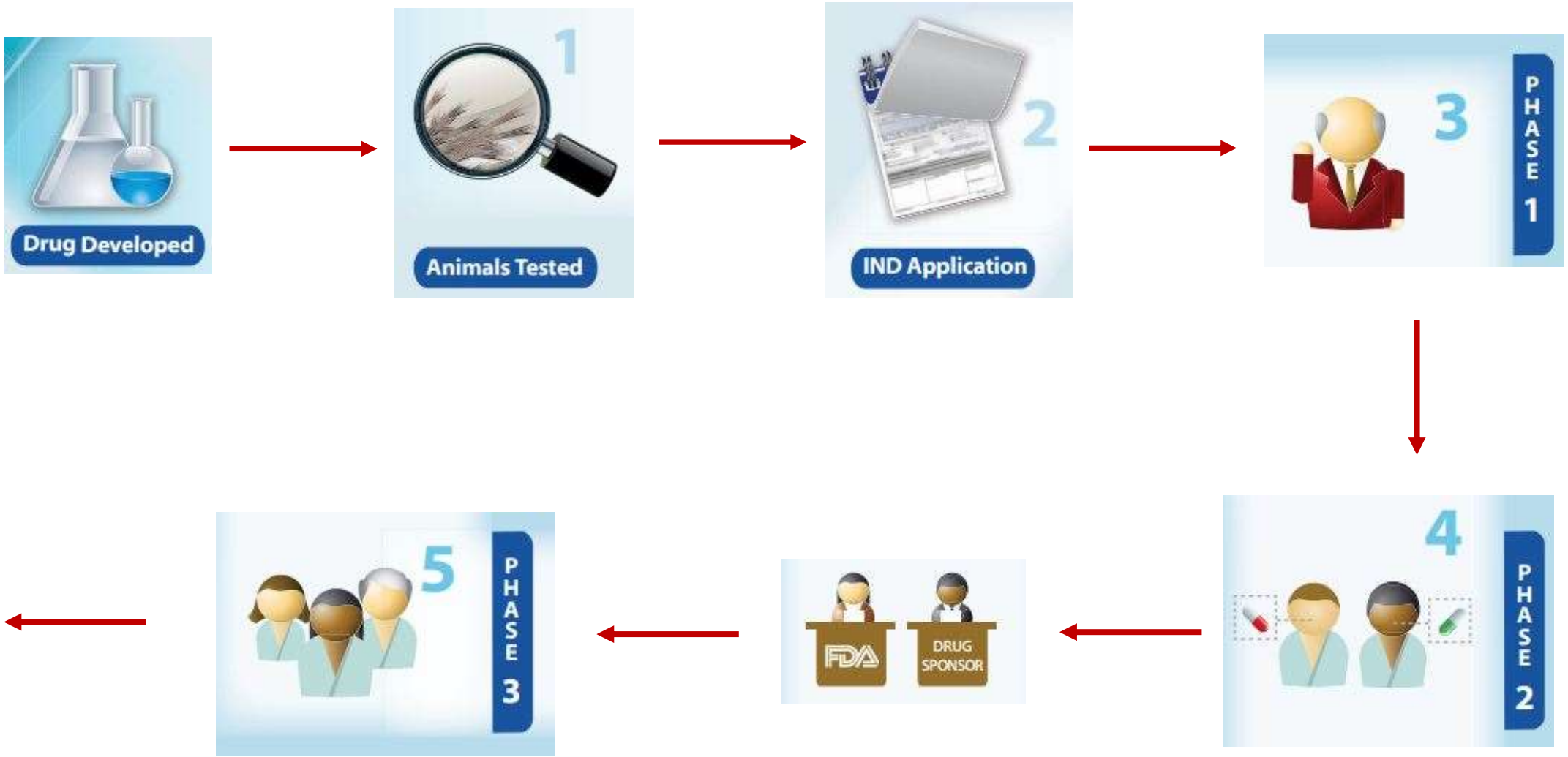
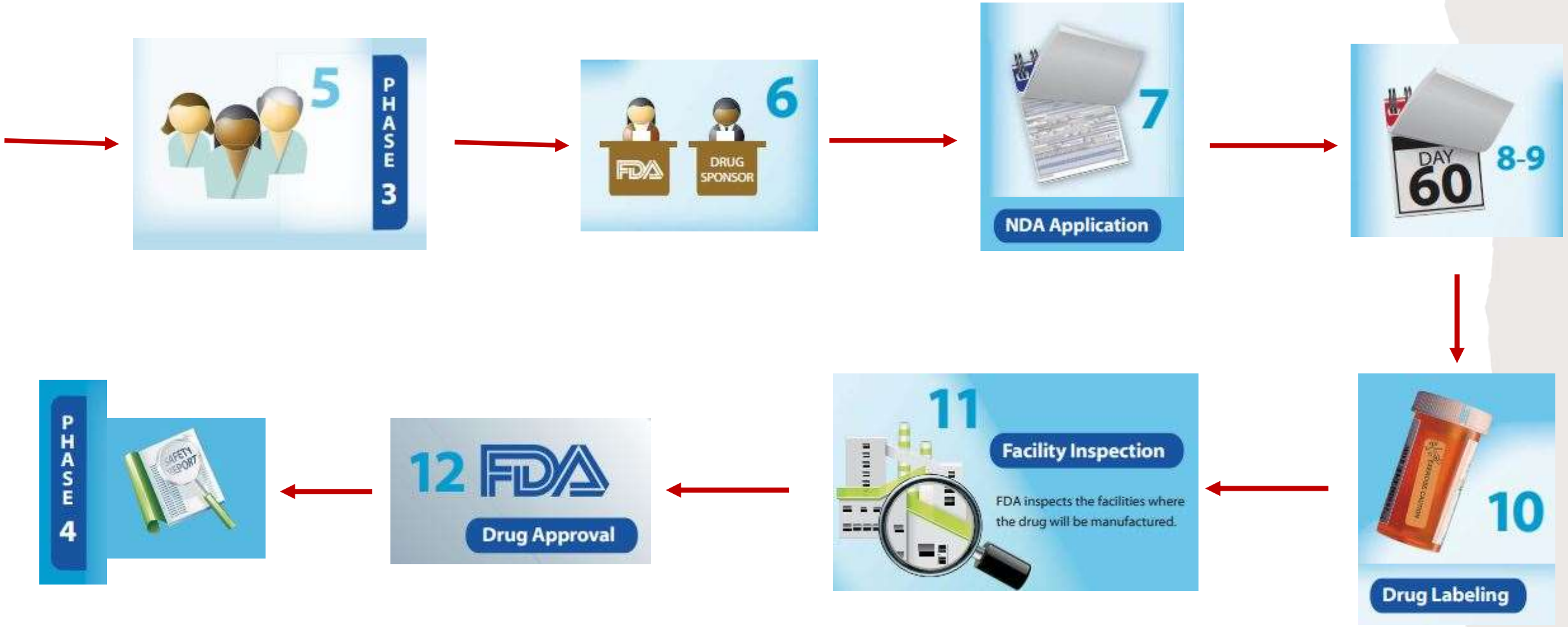
*FDA **does not** regulate clinical practice – once a medical product is made available to patients on the market, clinicians are able to prescribe it for other off-label uses.

FDA APPROVAL PROCESS



Source: FDA

FDA APPROVAL PROCESS (CONT'D)

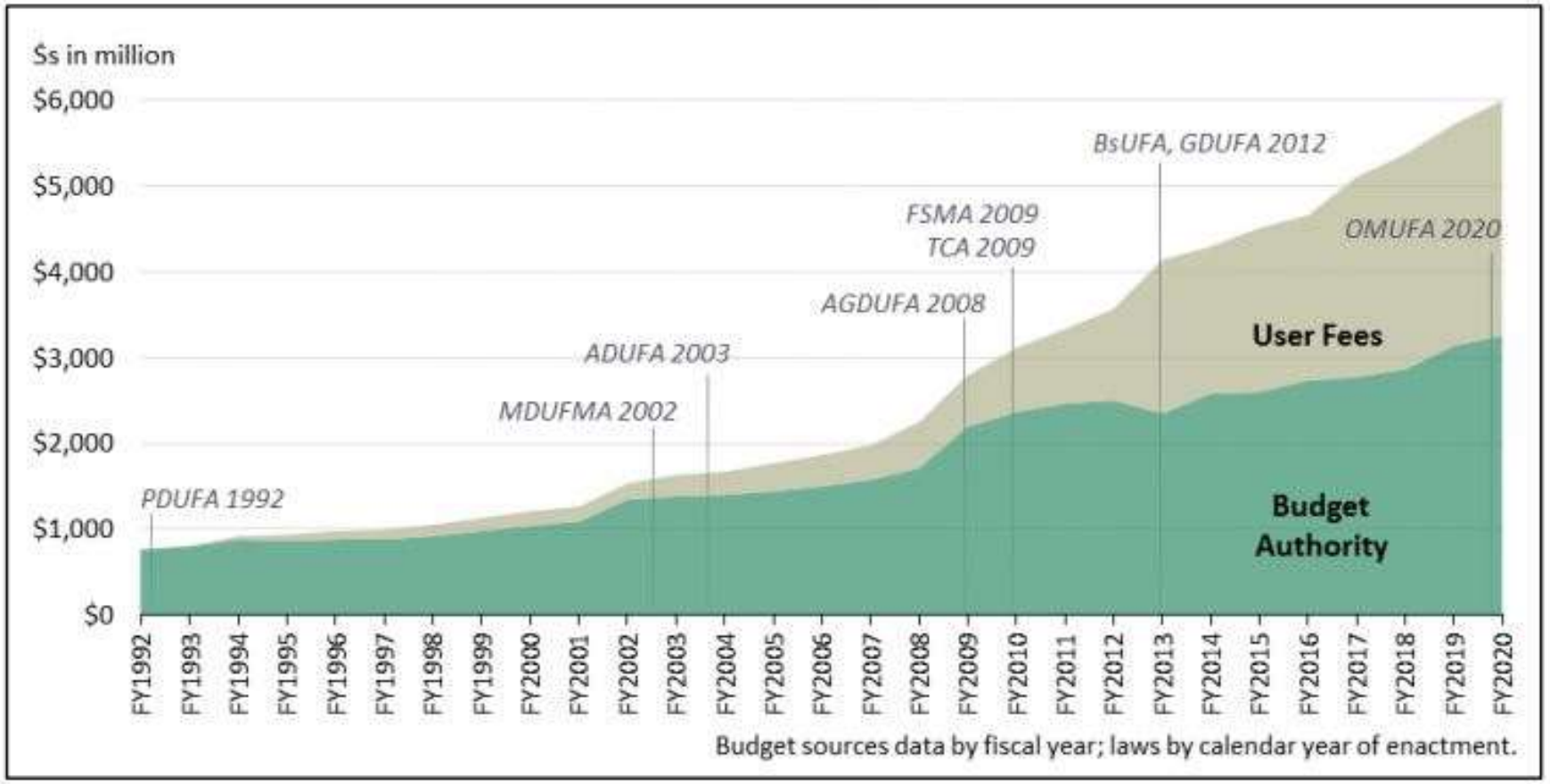


Source: FDA

ENSURING AN INDEPENDENT REGULATOR

Figure 1. FDA Spending, by Source, FY1992-FY2020

(in millions of dollars)



Source: Figure created by CRS using the FY1992 through FY2022 FDA CJs.

Original Investigation | Health Policy

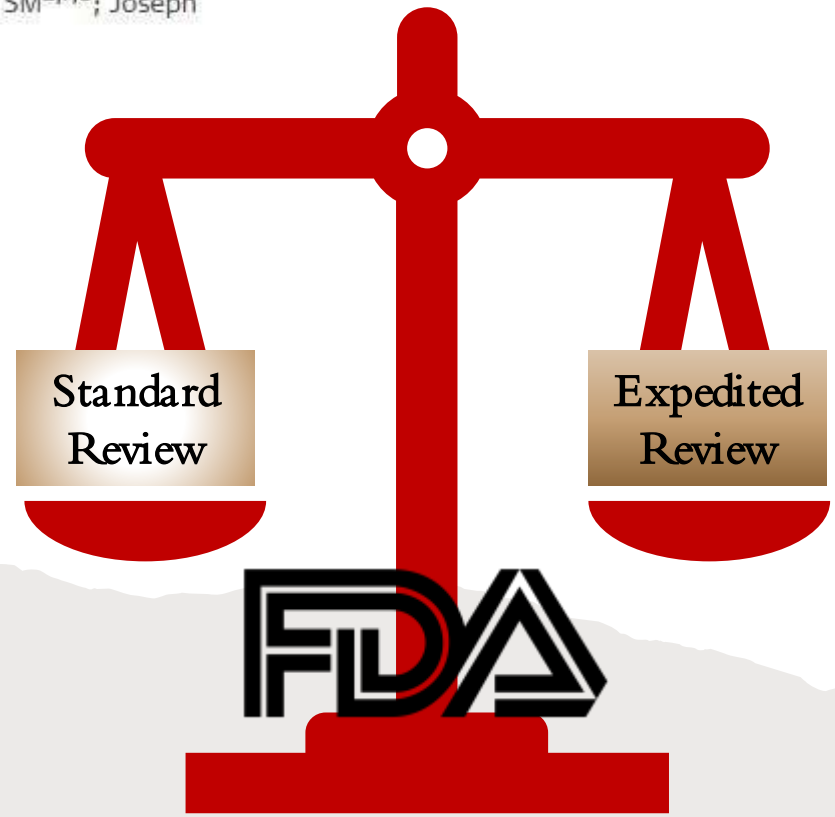
April 21, 2020

Assessment of Clinical Trials Supporting US Food and Drug Administration Approval of Novel Therapeutic Agents, 1995-2017

Audrey D. Zhang, AB[1,2]; Jeremy Puthumana, MS[3]; Nicholas S. Downing, MD[4,5]; Nilay D. Shah, PhD[6]; Harlan M. Krumholz, MD, SM[2,7,8]; Joseph S. Ross, MD, MHS[2,8,9,10]

» Author Affiliations | Article Information

JAMA Netw Open. 2020;3(4):e203284. doi:10.1001/jamanetworkopen.2020.3284



SHIFTING THE SCALES

THANK YOU

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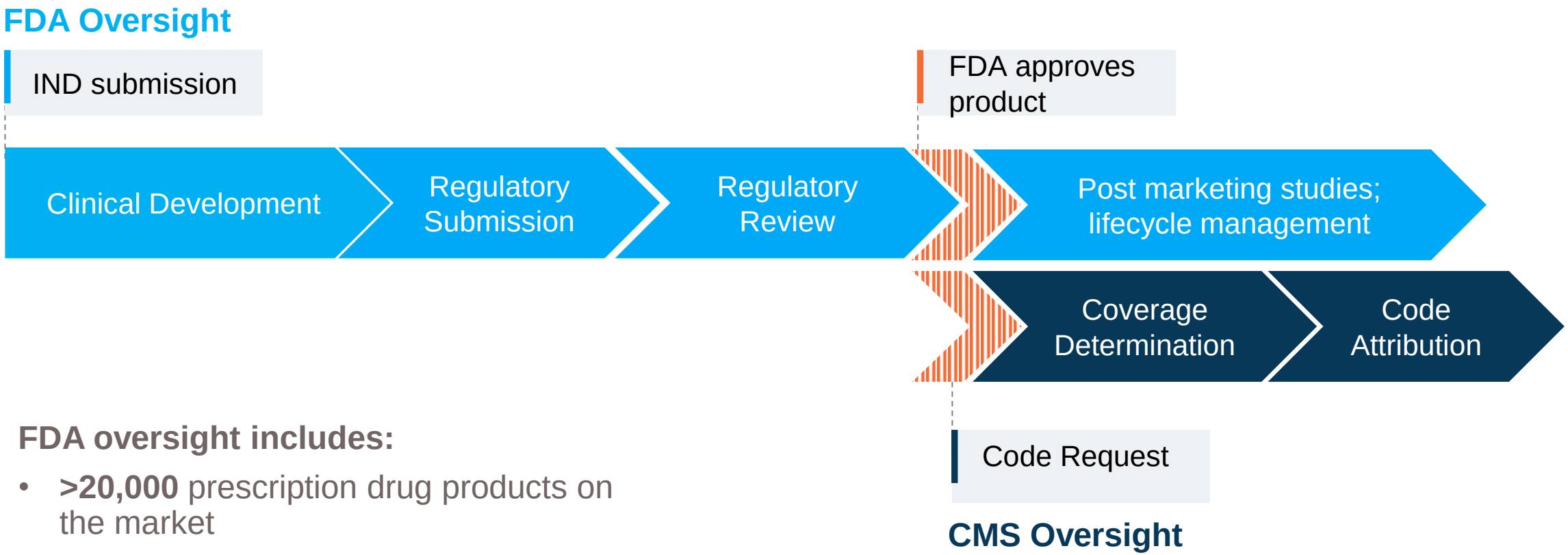
Avalere Health | A Fishawack Company
June 29th, 2022

Agency Oversight is Across Entire Lifecycle and Requires Resource Allocation Decisions



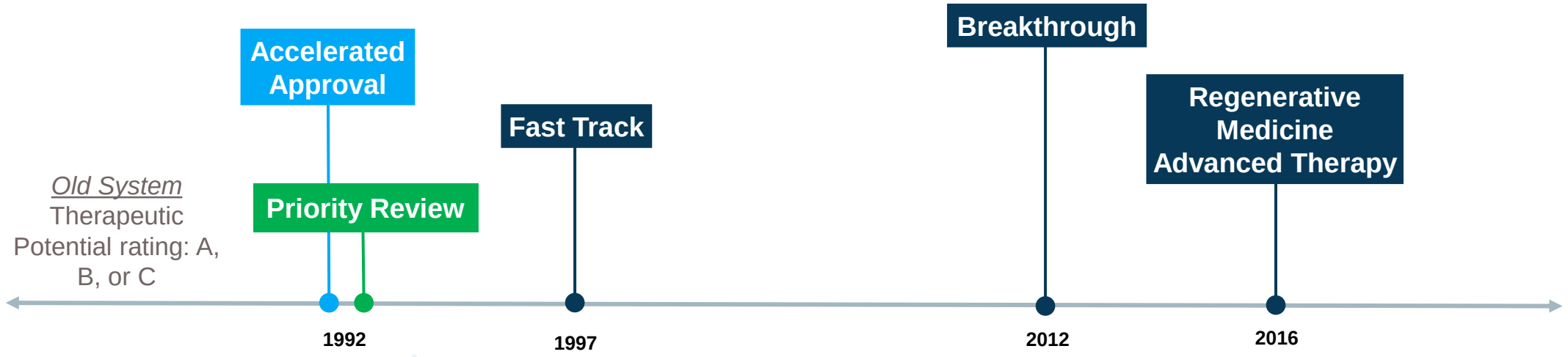
FDA oversight includes:

- **>20,000** prescription drug products on the market
- **>13,000** facilities for drug products
- **100,000** pages = typical application

Agency and Congress Aim to Speed High Value Products

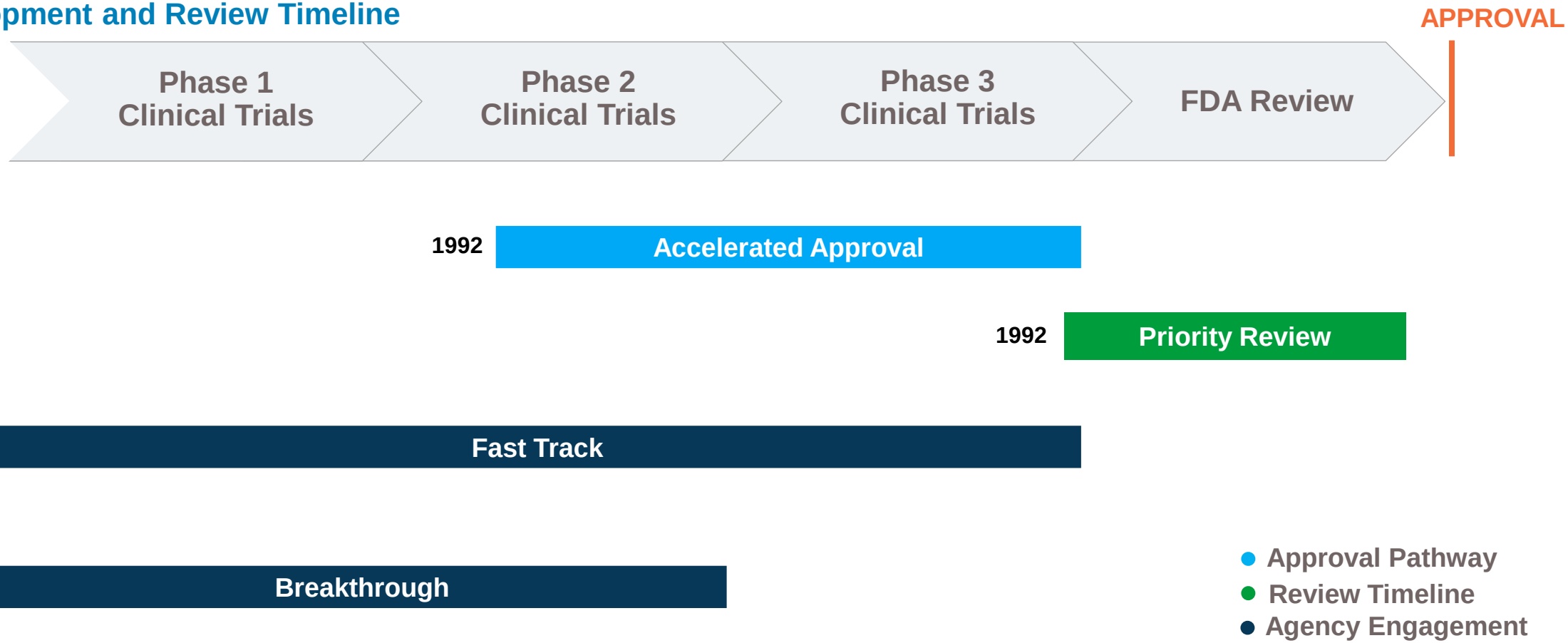
Evolving Approach Toward Targeted Expedited Programs

- Requires identification of high value product and prioritization of workflow, agency energy
- Previous system was less defined or transparent and assessed products based on therapeutic gains over existing products
- Historical events (AIDS epidemic, “drug lag”) play a large role in shaping policies
- Current expedited pathways and designations created over 30 years



Expedited Programs Impact Various Points in Development

Development and Review Timeline



Expedited Programs Target Specific High Value Products

Development and Review Timeline

1992 **Accelerated Approval**

Criteria: Serious or life-threatening disease with long term endpoints; Difficult to measure efficiently in trials

1992 **Priority Review**

Criteria: Significant improvement in safety/efficacy

1997 **Fast Track**

Criteria: Lifesaving treatment; patients in need

2012 **Breakthrough**

Criteria: Substantial improvement over available therapy

- Approval Pathway
- Review Timeline
- Agency Engagement

Additional Tools to Ensure High Value Products Continually are Developed and Incentivized

Unfair Trade
Monitored by Fair Trade Commission, Congress

- Protects against anticompetitive behavior and deceptive or unfair trade practices
- Advertising and promotional communications

Patent Protection
Monitored by US PTO

- Utilized to protect intellectual property at any point in development
- Expire after 20 years per statute; standalone expiration timeline

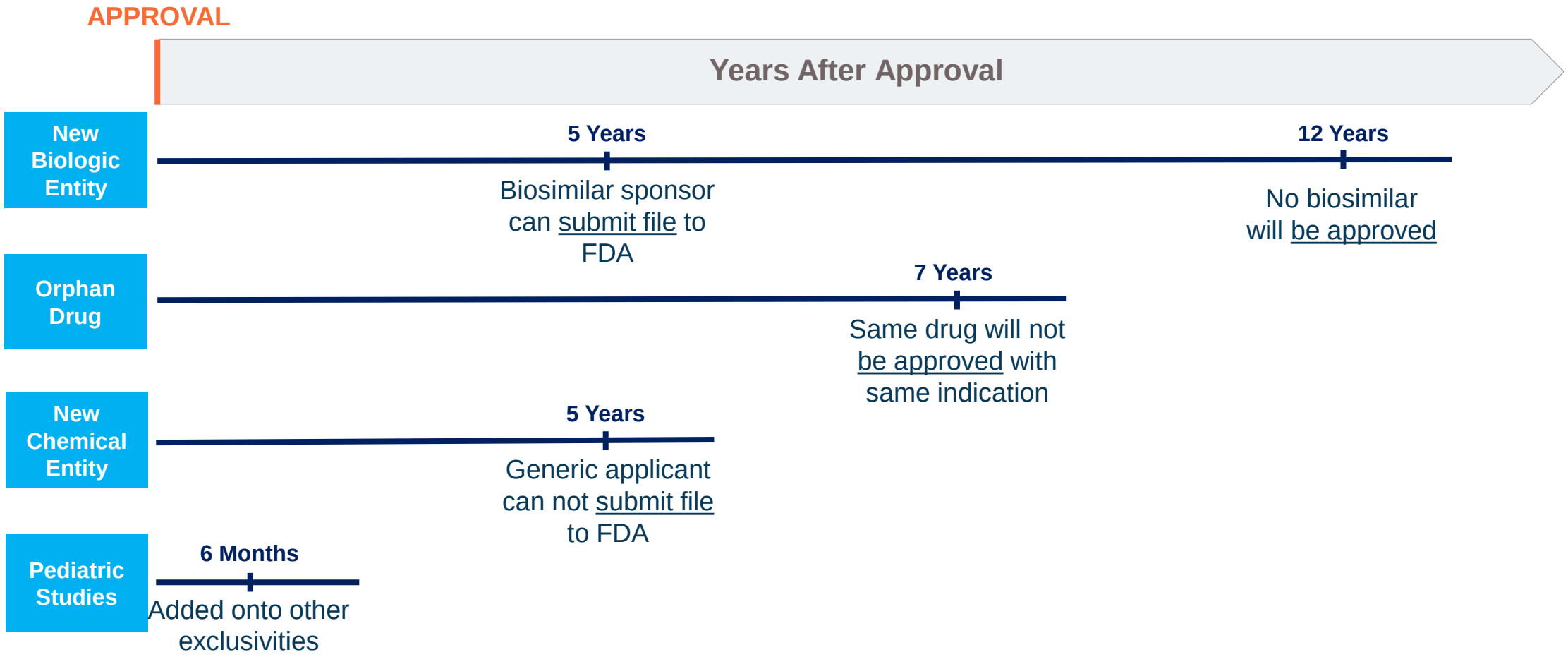
Market Exclusivity
Monitored by FDA

- Utilized to promote competition and innovation
- Contingent upon regulatory approval as well as statutory requirements
- Vary in duration

Many different approaches exist to create a sustainable marketplace for high value medical products. Each of these are in place to create a careful balance of innovation and competition while maintaining a fair market.

FDA: US Food and Drug Administration; PTO: Patent and Trademark Office

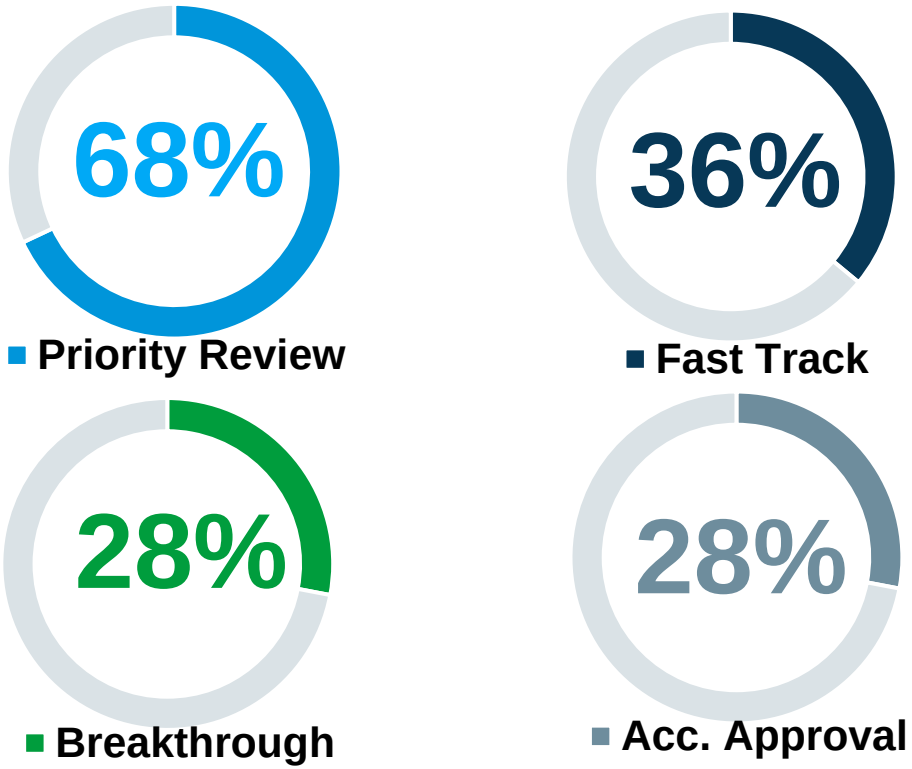
FDA Exclusivities Provide Marketing Rights for Specified Time

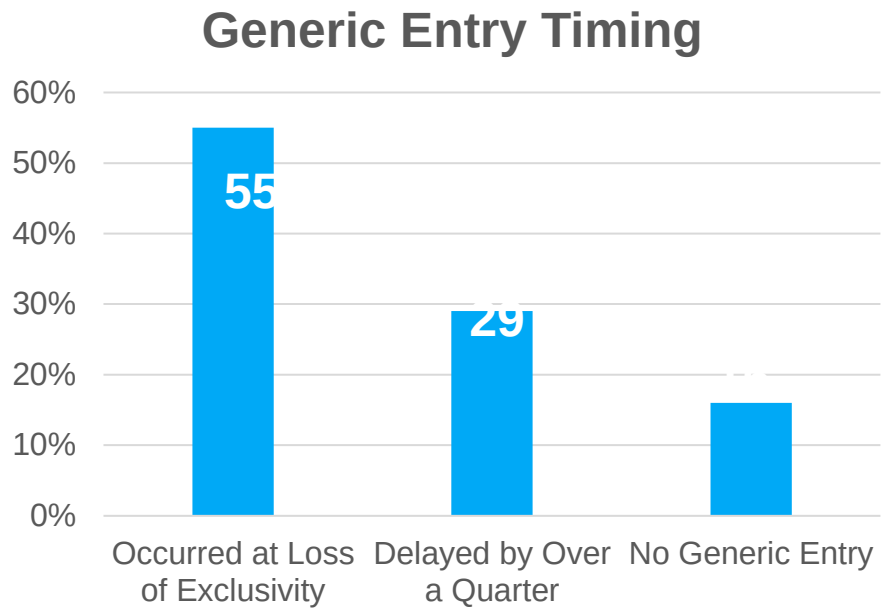


These provide exclusive marketing rights granted by FDA upon approval of a product which meets the specific criteria. The goal is to provide incentive to innovate and temporary protection from competition

Where Are We Now?

74% of Novel Products are ‘Expedited’





12.5 years

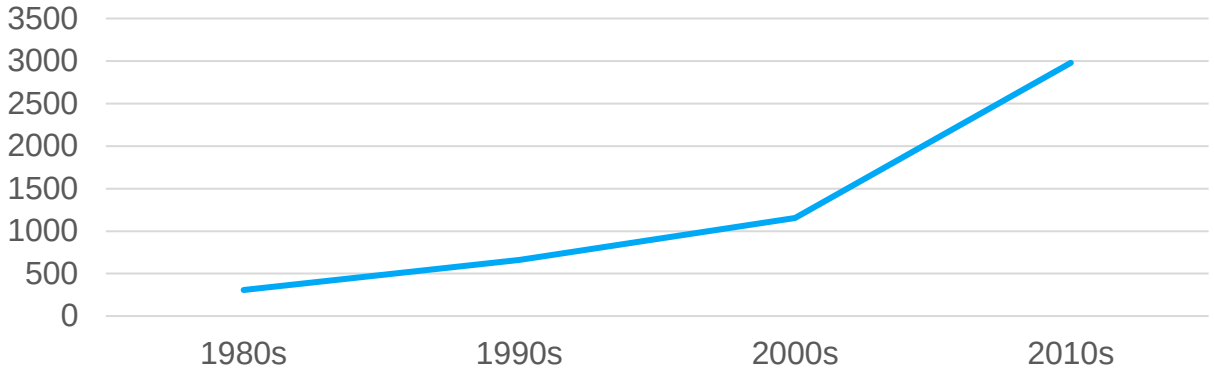
Average years small molecule drug is on the market before competition

FDA CDER Report: Advancing Health Through Innovation: New Drug Therapy Approvals in 2021
CDER: Center for Drug Evaluation and Research
Health Affairs: Estimating The Cost Of Delayed Generic Drug Entry To Medicaid link
Variations in time of market exclusivity among top-selling prescription drugs in the United States. JAMA Intern Med. 2015;175(4):635–7. link

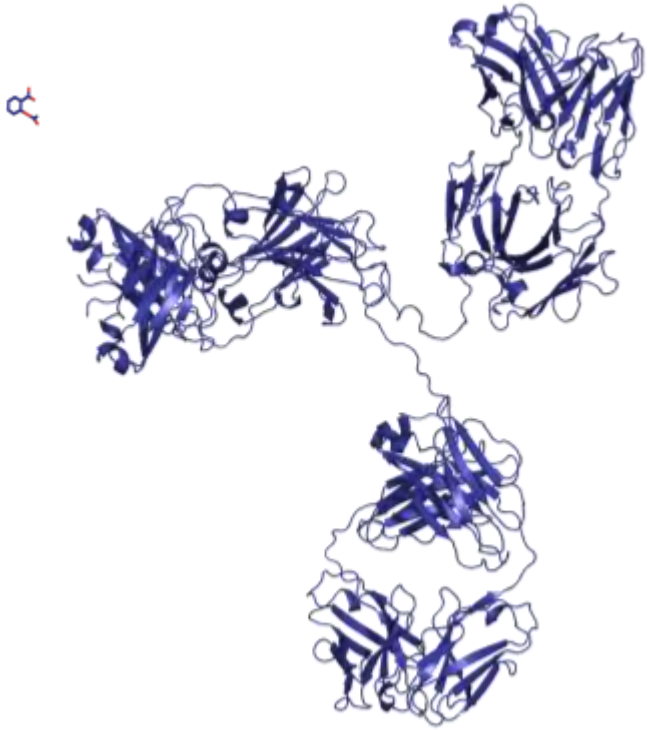
Changing Environment – Trends Will Require Efficiency

As the landscape of drug development continues to shift, we will need to continue to reform incentive structures

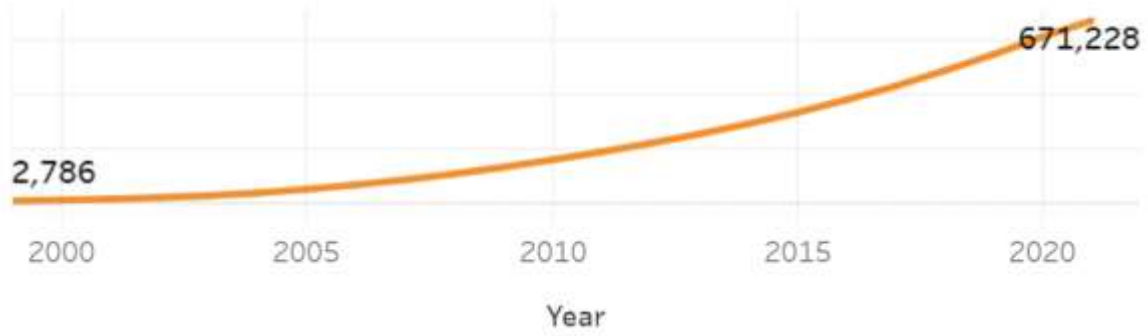
More Orphan Drugs, Products for Small Population*



More Complex Products



More Clinical Trials Being Run**



*2021 Jun 9;16(1):265. Using four decades of FDA orphan drug designations to describe trends in rare disease drug development link
** WHO Report Published Feb 2022: link

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Appendix

Details of FDA's Expedited Programs

Program	Eligibility Criteria	Potential Benefits
Intended to Speed Drug Development		
Fast Track (1997)	Nonclinical or clinical data demonstrate the potential to **address unmet medical need** of serious condition	Earlier FDA interaction, expedites drug development, application review
Breakthrough Therapy (2012)	Preliminary clinical data demonstrate **substantial improvement** on a clinically significant endpoint(s) over available therapies	Earlier FDA interaction, could considerably shorten drug development timelines
Regenerative Medicine Advanced Therapy (2017)	Preliminary evidence of clinical benefit has the potential to address unmet medical need in a serious condition.	Earlier FDA interaction, expedites drug development, application review
Intended to Speed FDA Review		
Priority Review (1992)	Shows **significant improvement in safety or effectiveness** over available therapies for serious condition	Accelerates marketing application review to 6 months rather than 10
Intended to Modify Approval Pathway		
Accelerated Approval (1992)	Evidence to support meaningful advantage over available therapies AND demonstrates an effect on a **surrogate endpoint** that is **reasonably likely** to predict clinical benefit, or on a clinical endpoint reasonably likely to predict effect on IMM	Faster clinical trials **for drugs with long-term clinical benefit**.

https://www.fda.gov/patients/learn-about-drug-and-device-approvals/fast-track-breakthrough-therapy-accelerated-approval-priority-review

Details of FDA Market Exclusivities

Exclusivity Type	License Type	Duration	Details
New Chemical Entity	NDA	5 years	Generics cannot file ANDA until 5 years is up (4 years if patent challenge)
New Biologic Entity	BLA	12 years	Biosimilars cannot file BLA until 4 years after
Orphan Drug Exclusivity	NDA or BLA	7 years	<200k individuals affected or impossible to recover cost of development
New Clinical Investigation	NDA or ANDA	3 years	Brand or generic with new "essential" clinical study
Pediatric Exclusivity	NDA or BLA	6 months	Added to existing exclusivity
Generating Antibiotic Incentives Now	NDA (theoretical BLA)	5 years	Added to existing exclusivity
180-day Exclusivity for Generics	ANDA	6 months	First generic ANDA filter with paragraph IV
Competitive Generic Therapy	ANDA	6 months	Requires "inadequate generic competition" of brand drug
Interchangeable Biologic	BLA	1 year	Related only to interchangeability

FFD&C: Federal Food Drug and Cosmetics; ANDA: Abbreviated New Drug Application; NDA: New drug application; BLA: Biologics licensing application; PHS: Public health services; BPCA: Best Pharmaceuticals for Children Act; FDASIA: FDA Safety and Administration Act FDAMA: FDA Modernization Act CFR: Code of BPCI: Biologics Price Competition and Innovation
Source: link

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FDA Drug Approval Pathways 101

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Following FDA Approval of a New Drug

- No national health technology assessment of:
  - Comparative effectiveness (e.g., Germany) or comparative cost-effective (e.g., England)

Health Technology Assessment in the U.S. – A Vision for the Future

- Handcuffed payers
  - Medicaid
    - Must generally cover all FDA-approved drugs
    - CMS rejected Massachusetts' waiver request to institute closed formulary in 2018
  - Medicare
    - Must cover all drugs in six classes: anticonvulsants, antidepressants, antineoplastics, antipsychotics, antiretrovirals, immunosuppressants
    - Otherwise must be "reasonable and necessary"
    - CMS prohibited from negotiating on behalf of Part D plans

- Aggressive marketing: ~$30 billion on drugs, disease awareness, lab tests, and health services in 2016
  -Schwartz & Woloshin. JAMA (2019).

- Soaring net launch prices and price increases
  -Rome et al. JAMA (2022); Hernández et al. JAMA (2020).


Sound, Fury and Prescription Drugs

Despite talk of reform, drug prices keep climbing.

Shift from Pre- to Post-Market Assessment

- The FDA is fast
  - Overall median time to total approval 2019: ~9 months
  - 2020: 68% of new drugs qualified for an expedited development or review pathway
- Approval on less rigorous evidence

> When considering the aggregate pivotal trials supporting each indication approval, the proportion of indications supported by at least 2 pivotal trials decreased (80.6% [95% CI, 72.6%-87.2%] in 1995-1997; 60.3% [95% CI, 47.2%-72.4%] in 2005-2007; and 52.8% [95% CI, 42.9%-62.6%] in 2015-2017; $P < .001$). The proportion of indications supported by only single-group pivotal trials increased (4.0% [95% CI, 1.3%-9.2%] in 1995-1997; 12.7% [95% CI, 5.6%-23.5%] in 2005-2007; and 17.0% [95% CI, 10.4%-25.5%] in 2015-2017; $P = .001$), whereas the proportion supported by at least 1 pivotal trial of 6 months' duration increased (25.8% [95% CI, 18.4%-34.4%] in 1995-1997; 34.9% [95% CI, 23.3%-48.0%] in 2005-2007; and 46.2% [95% CI, 36.5%-56.2%] in 2015-2017; $P = .001$).

-Zhang et al. JAMA Network Open (2020).

  - May result in earlier access to some safe and effective therapies
  - May also result in more drugs later found to be unsafe or ineffective

More Drugs But How Good and for What Conditions

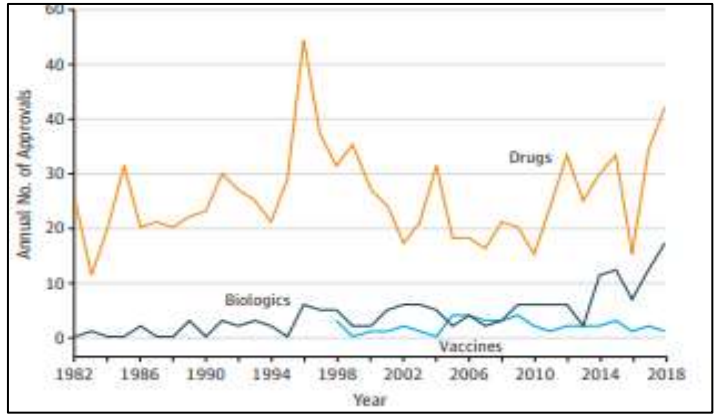
- There has been an increasing number of drug approvals over time
  - Mean annual number of approvals
    - 1990-1999: 25
    - 2010-2019: 40

News > Medscape Medical News

FDA Approved Record Number of Drugs in 2018

-Medscape (2019).

FDA Approvals By Year



-Darrow et al. JAMA (2020).

- Variable quality
  - Some new drugs have proven clinically transformational

    e.g., sofosbuvir (Sovaldi), tisagenlecleucl (Kymriah)
  - BUT of all new drugs approved by FDA in 2017, about two-thirds were rated by exert organizations in Germany, France, and Canada to offer no or minor additional benefits over existing treatments

-Frank et al. Health Affairs Forefront (2020).

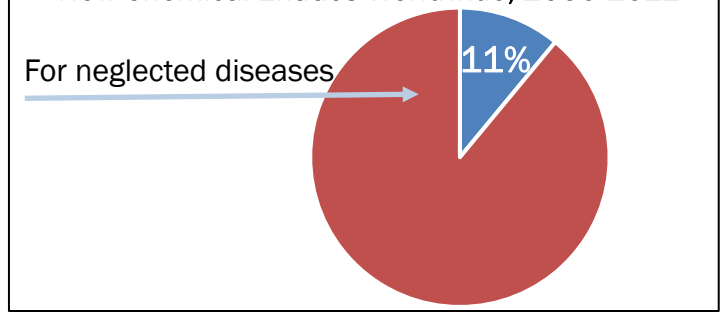
BRIEF

Amgen exits neuroscience R&D as pharma pulls back from field

-Biopharma Dive (2019).

- Disproportionate focus
  - On lucrative markets: oncology and orphan products
  - Away from risky/non-profitable markets: central nervous system and tropical diseases

New Chemical Entities Worldwide, 2000-2011



-Pedrique et al. Lancet Global Health (2013).

Accelerated Approvals

- As of May 2022, 278 drugs have been approved under the accelerated approval pathway
- Most common indications: oncology and rare diseases
- Challenges
  - High cost, uncertain benefits
    - Medicaid: 9.1% net spending despite only 0.4% of prescription use
      -Sachs et al. JAMA Health Forum (2021).
    - Aducanumab (Aduhelm)
      - List price $56,000 vs. $3,000-$8,000 per year cost-effective price
        -ICER (2021).
      - November 2021, CMS announced largest increase in premiums in 15 years
  - Minimal incentives to complete required post-approval trial, limited enforcement
    - 1992-2016=13% of accelerated approvals, of which 13% were on the market a median of 9.5 years without confirmatory evidence
      -ICER (2021).
    - FDA gives Biogen up to 9 years to complete Phase 4 study for aducanumab
- Lengthy process for withdrawing indication (e.g., hydroxyprogesterone caproate (Makena)
- Result: greater gatekeeping role by payors (e.g., coverage with evidence determination)

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30 YEARS

FDA Approval Pathways 101: Current Political Environment

Presented by Clay Alspach
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June 29, 2022

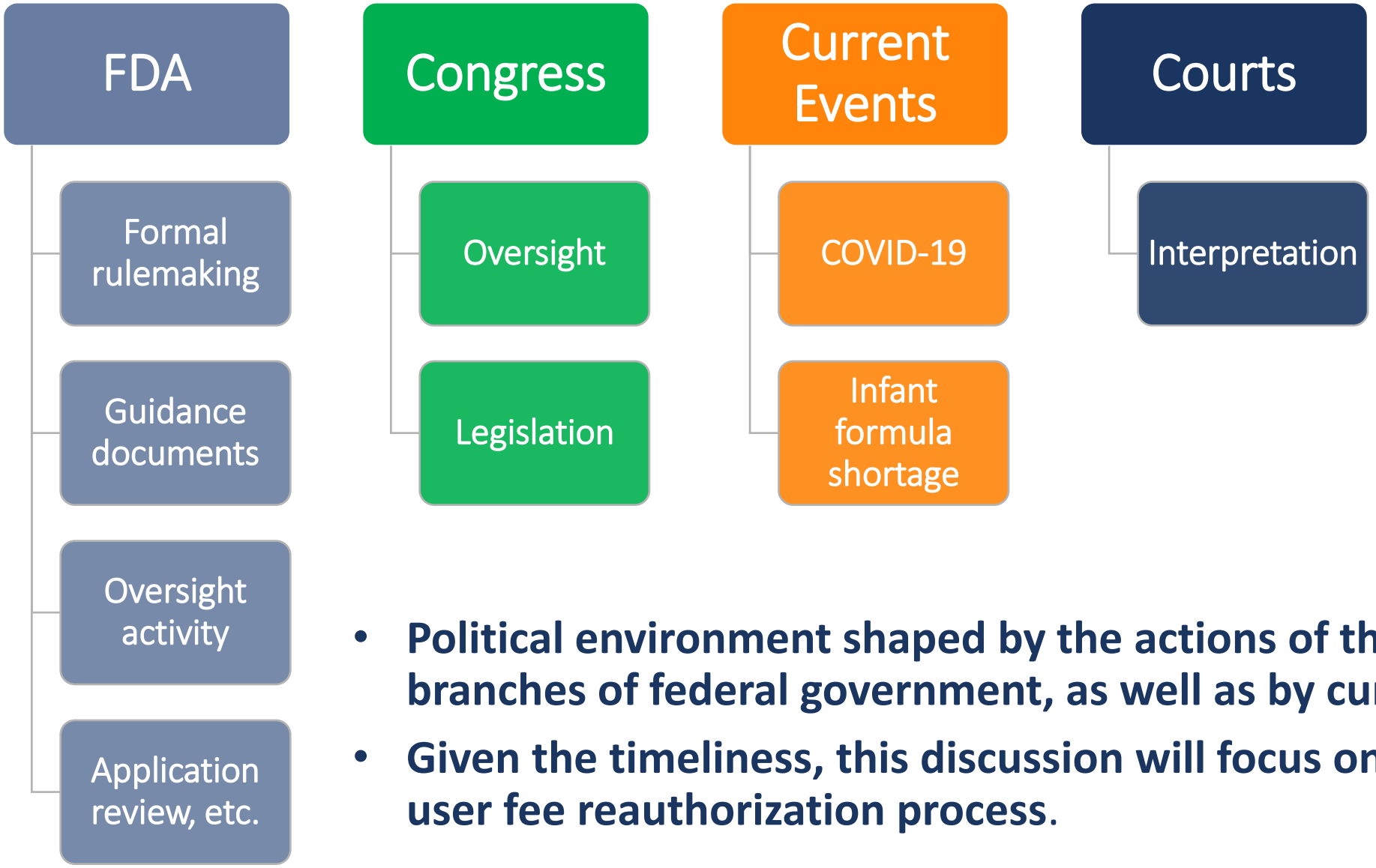
LEAVITT PARTNERS

Outline

- Political Environment
- Background: FDA User Fees and Reauthorization Effort
- Examples of Past Congressional Efforts
- Current Congressional Efforts
- Concluding Thoughts

Current Political Environment

Current Political Environment



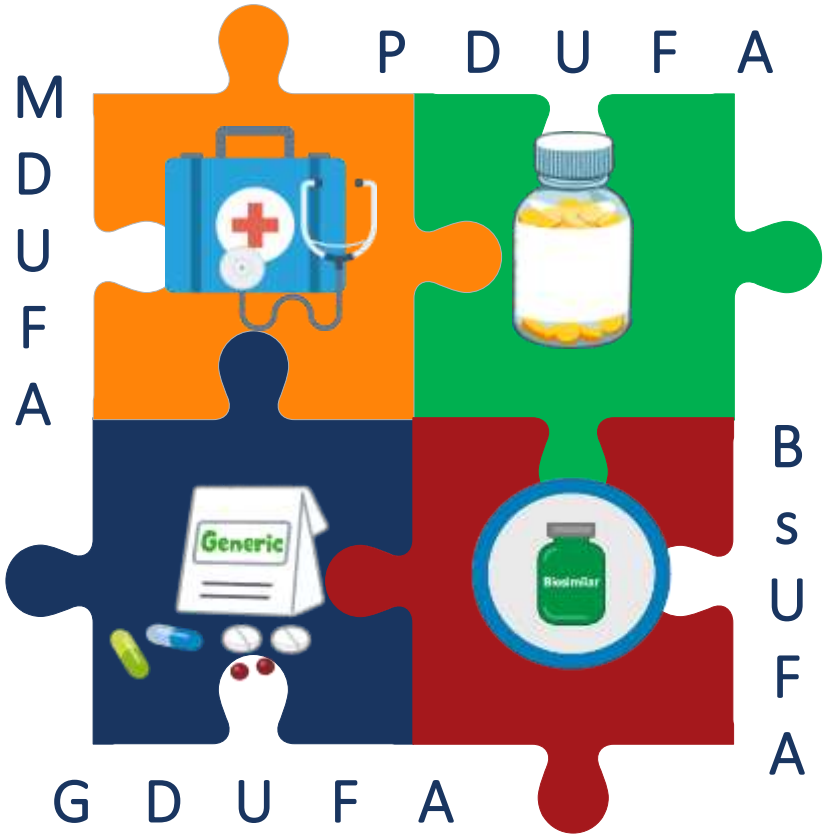
- **Political environment shaped by the actions of the three branches of federal government, as well as by current events.**
- **Given the timeliness, this discussion will focus on the FDA user fee reauthorization process.**

What is the FDA User Fee Process?

FDA Drug User Fee Reauthorization Overview

FDA review of medical products is funded through a combination of annual discretionary appropriations from Congress and user fees collected from the industry.

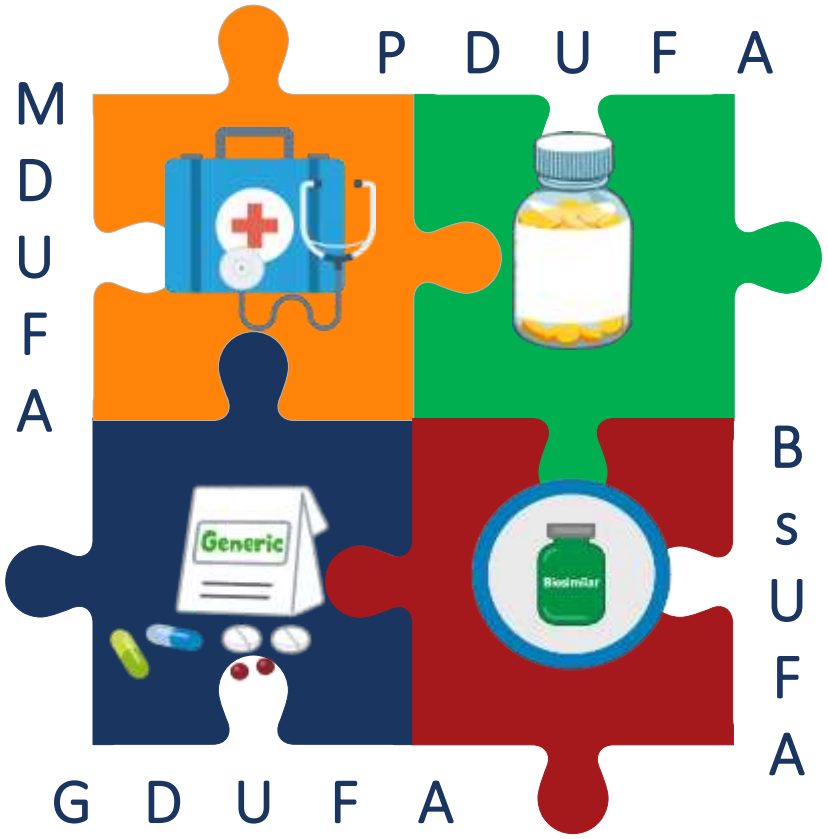
- User fee amendment programs require Congressional reauthorization every five years.
  - UFAs expire at the end of September 2022, but Congress wants to finish work by end of July to avoid “pink slip” issue at FDA.
- Major user fee programs
  - **Prescription Drug User Fee Act (PDUFA)**
    - Seventh reauthorization
  - **Generic Drug User Fee Act (GDUFA)**
    - Third reauthorization
  - **Medical Device User Fee Act (MDUFA)**
    - Fifth reauthorization
  - **Biosimilar User Fee Act (BsUFA)**
    - Third reauthorization



FDA Drug User Fees Overview Cont'd

- **Congress usually utilizes the reauthorization process to:**
  1. Reauthorize the FDA user fees.
  2. Conduct oversight of FDA.
  3. Enact policy reforms.

- **As part of the process, Congress and FDA will consider overarching issues such as:**
  - Innovation
  - Access
  - Safety



Examples of Past Congressional Efforts

Example 1 (FDAMA (1997))

FOOD AND DRUG ADMINISTRATION
MODERIZATION ACT OF 1997

Example 2 (FDAAA (2007))

Food and Drug Administration Amendments Act (FDAAA) of 2007

TITLE IX—ENHANCED AUTHORITIES REGARDING POSTMARKET SAFETY OF DRUGS

Subtitle A—Postmarket Studies and Surveillance

Subtitle B—Other Provisions to Ensure Drug Safety and Surveillance

Example 3 (FDASIA (2012))

Food and Drug Administration Safety and Innovation Act (FDASIA)

PUBLIC LAW 112–144—JULY 9, 2012 126 STAT. 995

TITLE IX—DRUG APPROVAL AND PATIENT ACCESS

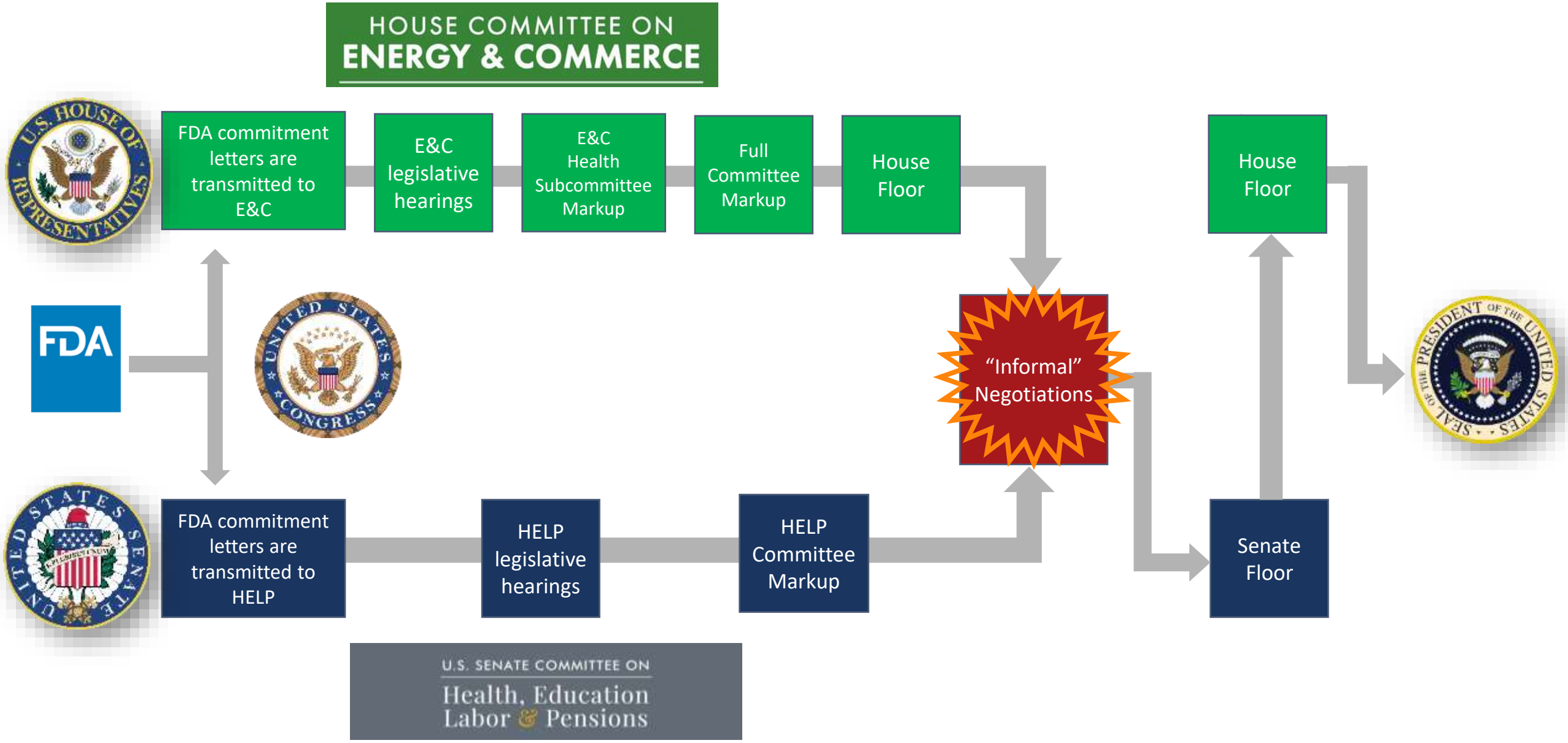
Example 4 (FDARA (2017))

FDA Reauthorization Act of 2017 (FDARA)

TITLE VI—REAUTHORIZATIONS AND IMPROVEMENTS RELATED TO DRUGS

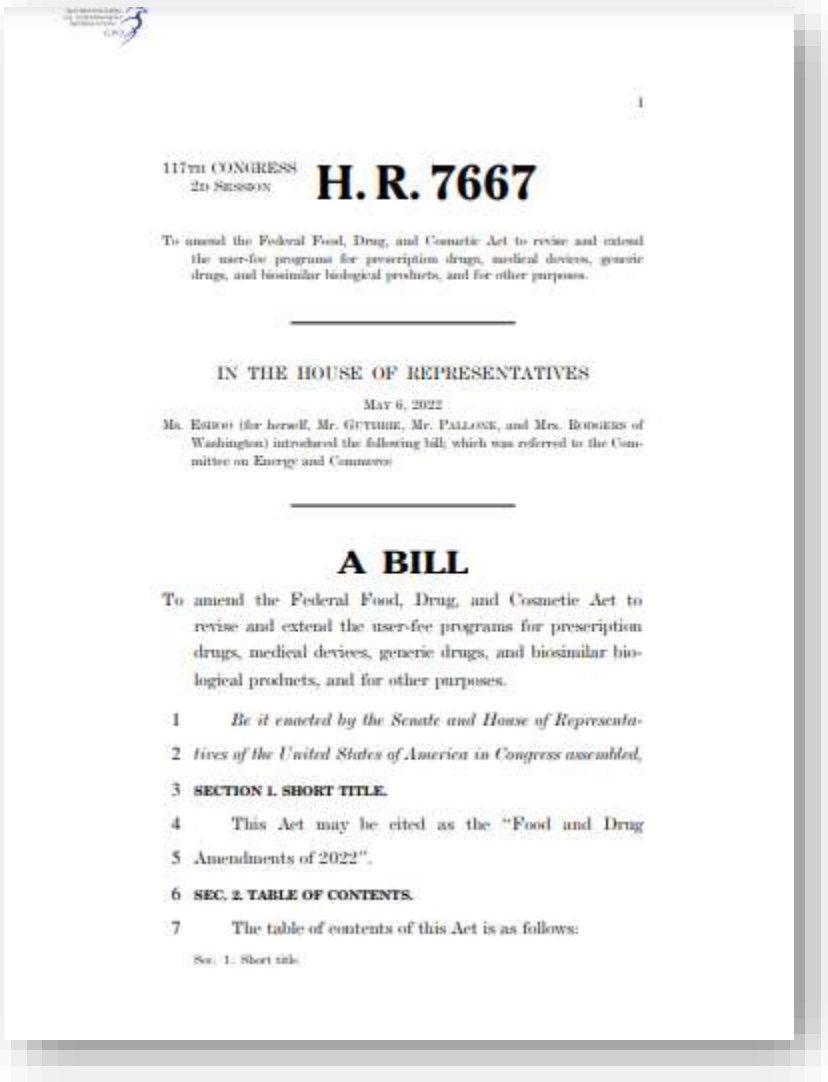
Current FDA User Reauthorization Efforts

Possible User Fee Reauthorization Legislative Process



House Bill

- **Timing:**
  - House passed on June 8 by a bipartisan 392-28.
- **Key provisions (Accelerated Approval):**
  - Requires FDA to specify conditions for required post approval studies for drugs approved under accelerated approval by the time the drug is approved.
    - May include enrollment targets and milestones, including the target date for study completion.
  - Authorizes FDA to require post approval studies to be underway at the time of approval for such drugs and requires FDA to explain any instances where it does not require such studies.
    - Studies may be supported by real world evidence.
  - Clarifies that existing authority to withdraw approvals where sponsors fail to conduct studies with due diligence applies with respect to the approval conditions and streamlines procedures for withdrawal of approval.
  - Codifies labeling requirements for accelerated approval and information on surrogate endpoints and requires more frequent reports on post approval study progress.



117TH CONGRESS
2D SESSION

H. R. 7667

To amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs, medical devices, generic drugs, and biosimilar biological products, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MAY 6, 2022

MS. ESHOO (for herself, MR. GUTHRIE, MR. PALLONE, and MRS. RODGERS of Washington) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs, medical devices, generic drugs, and biosimilar biological products, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Food and Drug Amendments of 2022".

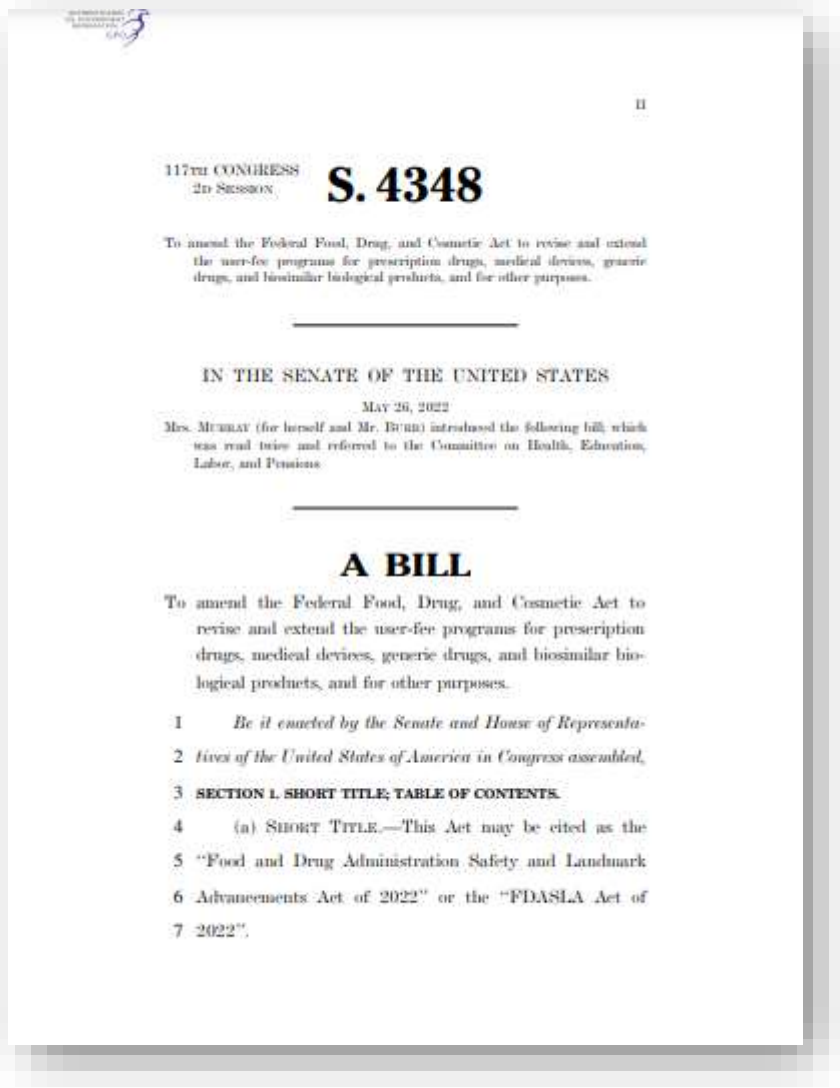
SEC. 2. TABLE OF CONTENTS.

The table of contents of this Act is as follows:

Sec. 1. Short title

Senate

- **Timing:**
  - HELP Committee passed S. 4348 on June 14 by a 13-9 vote.
- **Key provisions (Accelerated Approval):**
  - Requires the FDA to provide a summary of the basis of approval for a drug approved through the accelerated approval pathway, including whether an advisory committee meeting was held, and the rationale for determining the surrogate endpoint is reasonably likely to predict clinical benefit.
  - Requires that sponsors of drugs approved under accelerated approval submit to the Secretary a report of progress on required post approval studies every 180 days.
  - Requires the Secretary to establish an intra-agency coordinating council within FDA to ensure the consistent and appropriate use of the accelerated approval pathway.
  - Requires FDA to publish on the FDA website why a study is not appropriate or necessary, if FDA does not require that a product approved under accelerated approval conduct a post approval study.



II

117TH CONGRESS
2D SESSION

S. 4348

To amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs, medical devices, generic drugs, and biosimilar biological products, and for other purposes.

IN THE SENATE OF THE UNITED STATES

MAY 26, 2022

Mrs. MURRAY (for herself and Mr. BURR) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs, medical devices, generic drugs, and biosimilar biological products, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

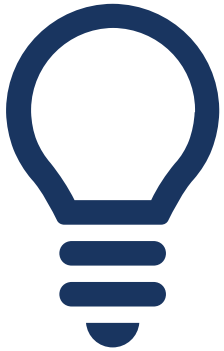
SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the "Food and Drug Administration Safety and Landmark Advancements Act of 2022" or the "FDASLA Act of 2022".

Concluding Thoughts

Concluding Thoughts

- The current political environment is incredibly fluid.
- FDA user fee reauthorization process will be a (if not thee) major focus over next several months, but other issues will arise (they will have an impact on the process and broader environment).
- The drug approval process, including the expedited programs, will continue to evolve as a result of advances in science, focus on access (pre- and post-market), and demand for more patient engagement (among other factors).
- Congressional debates and oversight on the approval process have an impact; legislation is the not the only factor.



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Please fill out the evaluation survey you will receive immediately after this presentation, or via email this afternoon!

www.allhealthpolicy.org

UPCOMING EVENT

July 15, 2022 | 12:00 pm ET – 1:30 pm ET

Policy Options to Ensuring Stable Coverage and Avoiding Premium Shocks

This event will outline the various coverage-related elements at play over the next six to nine months, their tradeoffs, and how they may impact various stakeholders including consumers, state leaders, and payers. Panelists will explore enrollment, risk pool, and premium forecasts, approaches that state and health plan leaders may take, as well as implications on overall costs to the system.

allh.us/events

THANK YOU FOR ATTENDING!

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